UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

MDL NO. 13-02419-RWZ

IN RE: NEW ENGLAND COMPOUNDING PHARMACY, INC.
PRODUCTS LIABILITY LITIGATION

MEMORANDUM OF DECISION

January 13, 2015

ZOBEL, D.J.

On February 7, 2014, defendants BKC Pain Specialists ("BKC"), Adil Kataby, M.D. ("Kataby"), and Nikesh Batra, M.D. ("Batra") (collectively "the BKC defendants"), sought dismissal of all claims against them in three cases[1] for failure to state a claim under Fed. R. Civ. 12(b)(1) & (6) (Docket # 897). For the reasons that follow, the motion is DENIED IN PART and ALLOWED IN PART.

I. Background[2]

A. The Multidistrict Litigation

This multidistrict litigation stems from an outbreak of fungal meningitis caused by contaminated methylprednisolone acetate ("MPA") manufactured and sold by the New England Compounding Pharmacy, Inc., d/b/a New England Compounding Center

[1] Montee v. BKC Specialists LLC. et al, No. 1:13-cv-12657, Cooper v. BKC Pain Specialists, LLC et al, No. 1:13-cv-12658, Cooper v. BKC Pain Specialist LLC et al, No. 1:13-cv-12659.

[2] A detailed account of the background of the case is set forth in previous opinions of the court. See, e.g., In re New Eng. Compounding Pharm., Inc. Prods. Liability Litig., 496 B.R. 256, 260-263 (D. Mass. 2013). Only a brief summary is outlined here.

("NECC"). NECC operated a compounding pharmacy in Framingham, Massachusetts, that combined and mixed ingredients to create specific formulations of pharmaceutical products. In the Fall of 2012, health officials traced a number of cases of fungal meningitis to injections of MPA that had been manufactured by NECC. NECC initiated a recall of several contaminated batches of MPA before eventually surrendering its pharmacy license and ceasing production of all pharmaceutical products. NECC filed for Chapter 11 bankruptcy in December 2012.

Lawsuits alleging death or injury caused by contaminated MPA were filed against NECC, affiliated entities and individuals, and/or health care providers in multiple state and federal jurisdictions around the country beginning in November 2012. In February 2013, the Judicial Panel on Multidistrict Litigation ("JPML") issued an order under 28 U.S.C. § 1407 transferring a number of cases pending in several federal courts to this court for coordinated and consolidated pretrial proceedings; subsequent JPML orders also transferred "tag-along" cases here. Other cases pending in both federal and state court were likewise transferred to this court via additional transfer orders. See In re New Eng. Compounding Pharm., Inc. Prods. Liability Litig., 496 B.R. 256 (D. Mass. 2013) (Docket # 176); In re New Eng. Compounding Pharm., Inc. Prods. Liability Litig., Civil Action No. 13-2419-RWZ, 2014 WL 2040139 (D. Mass. May 15, 2014) (Docket # 1131); June 4, 2014, Transfer Order (Docket # 1173).

On November 5, 2013, in accordance with MDL Order No. 6 (Docket # 209), the court-appointed plaintiffs' steering committee filed a master complaint against

numerous non-NECC parties including hospitals, clinics, and health care facilities (as well as their physicians, staff, agents, and employees) that allegedly obtained contaminated MPA from NECC and administered it to their patients.[3] See Master Complaint ("Master Compl."), Docket # 545. Plaintiffs who already had cases on file or who wished to file in the multidistrict litigation thereafter filed short-form complaints to assert facts and claims as set out in the master complaint.

B. The *Montee & Cooper Actions*

The three actions for decision here, Montee v. BKC Specialists LLC. et al, No. 1:13-cv-12657, Cooper v. BKC Pain Specialists, LLC et al, No. 1:13-cv-12658, Cooper v. BKC Pain Specialist LLC et al, No. 1:13-cv-12659, were all filed in the Northern District of Ohio before being transferred to the MDL docket. Plaintiff Montee alleges that Dr. Batra injected her with contaminated NECC MPA on September 4, 2012, and that she suffered injuries and damages as a result. Plaintiff Brandy Cooper alleges that Dr. Kataby injected her with contaminated NECC MPA on either or both of March 21, 2012 and May 30, 2012, and that she and her husband suffered damages as a result. Plaintiff Pamela Cooper alleges that Dr. Kataby injected her with contaminated NECC MPA on September 24 and October 1, 2012, and that she suffered damages as a result.

On February 7, 2014, defendants moved to dismiss the complaint for failure to state a claim.

[3] The master complaint was intended to be an administrative tool, allowing the allegations and claims against all defendants to be stated in one document.

II. Legal Standard

"To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (quoting Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 570 (2007)). When ruling on a motion to dismiss under Fed. R. Civ. P. 12(b)(6), the court accepts as true all factual allegations contained in the complaint, but not legal conclusions. Id. A complaint need only allege "enough factual matter (taken as true) to suggest" the validity of the claim. Twombly, 550 U.S. at 557. Where a motion is made pursuant to Fed. R. Civ. P. 12(b)(6) but centrally relies on an affidavit to dispute facts expressly pled in the complaint, the motion must be treated as one for summary judgment under Rule 56. Rosich v. Sur-Townsend Pontiac, Inc., No. 2:09CV155 PPS, 2010 WL 1930653, at *1 (N.D. Ind. May 11, 2010).

III. Discussion

A. Whether Brandy Cooper Was Injected With Contaminated MPA

As an initial matter, defendants attempt to rely on an affidavit of Dr. Kataby to dismiss the claims of plaintiff Brandy Cooper. The attached affidavit, Docket # 896 Exh. 1, disputes the claim that Brandy Cooper was injected with infected MPA, a fact alleged on the face of the complaint. Although the BKC defendants do not explicitly ask for consideration of that portion of their motion as one for summary judgment, as would be required to consider the affidavit, Rosich, 2010 WL 1930653, at *1, even if the court were to treat that portion of the motion as one for summary judgment there is ample evidence in the record, including documents produced by the defendants, to present

questions of material fact. That portion of defendants' motion to dismiss is, accordingly, denied.

B. Motion to Dismiss for Failure to State a Claim

Plaintiffs allege claims[4] against the defendants for common law negligence and gross negligence, violation of the Ohio Consumer Sales Practices Act (O.R.C. § 1345.01 *et seq*. and O.A.C. § 109:4-3-01 *et seq*.), statuory claims for product liability, failure to warn, and punitive damages.[5] Defendants assert that all these claims should be dismissed for failure to state a claim upon which relief can be granted.

1. Negligence and Gross Negligence (Count III)

To prove negligence under Ohio law, a plaintiff must plead sufficient facts to establish "the existence of a duty, a breach of the duty, and an injury proximately resulting therefrom." Middleton v. Rogers Ltd., Inc., 804 F. Supp. 2d 632, 639 (S.D. Ohio 2011).

a. Duty

Defendants argue that plaintiffs have failed to allege a duty because "Ohio law does not impose a duty on physicians and/or medical clinics to regulate the pharmacies from which they lawfully purchase medications, nor does Ohio law impose a duty on physicians to visit and/or evaluate a licensed pharmacy's compounding facility prior to purchasing medications as Plaintiff [sic] has alleged." Docket. # 897, p. 8.

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[4] I address the claims as plead and litigated, noting, however, that some of the "claims" are not, properly speaking, independent causes of action.

[5] Plaintiffs have voluntarily withdrawn their claims for agency, battery, and conspiracy. See Docket # 1513, Transcript of Status Conference and Motion Hearing held on Oct. 23, 2014, at 66.

Plaintiffs respond, however, that the relevant duty was "to exercise reasonable care when treating Plaintiffs." Docket # 1062 at 8. The master complaint alleges several cognizable duties within that duty of care:

- the duty to exercise reasonable care to ensure that the drugs they purchased to administer to their patients were procured from drug companies that complied with pharmaceutical laws, made safe and effective drugs, and utilized proper quality control, safety, and sterility measures;
- to exercise reasonable care to avoid administering contaminated drugs, or drugs they knew or should have known to be contaminated, to plaintiff;
- to provide plaintiff with reasonable care and treatment;
- to obtain informed consent from the plaintiff for the procedure performed, adequately and accurately describing the nature and risks of the procedure, including the drugs that were to be administered; and
- to inform plaintiff of the source of the drug (an unaccredited, mass producing, out-of state, compounding pharmacy, unregulated by the FDA) and the dangers associated therewith.

See Master Compl. at ¶¶ 226-232. The master complaint further alleges that defendants breached these duties by, among other things, failing to exercise reasonable and prudent care to ensure that the drug they purchased and provided to plaintiffs were made and sold in compliance with all applicable pharmaceutical laws; failing to follow certain policies and procedures to ensure such drugs were safe; failing to adequately supervise and train employees and agents who ordered the drugs; failing to promptly notify plaintiffs that they were injected with potentially contaminated steroids; and generally failing to exercise reasonable care to ensure they were not injecting contaminated and dangerous drugs into their patients. See id. at ¶ 234.

Plaintiffs further allege that the BKC defendants were negligent by furnishing "fake" patient lists to NECC to facilitate NECC's improper and illegal mass production of the MPA, in violation of Ohio's Board of Pharmacy regulations, Ohio Admin. Code 4729-5-30.

Such allegations of duty are sufficient to make out claims for negligence and gross negligence under Ohio law.

b. Causation

Defendants' argument concerning causation attempts to trace a causal connection from the breaches alleged against NECC, not the breaches alleged against the BKC defendants. Plaintiffs allege the BKC defendants were negligent in bulk-ordering, under false names, non-FDA approved preservative-free drugs, in violation of state regulations and in failing to inform plaintiffs of these facts. They further allege that the foreseeable and actual consequence was the patients' consenting to treatment that they otherwise would not have agreed to, and that such treatment led to their injuries. The fact that NECC's conduct was the cause of the contamination in the MPA does not preclude the BKC defendants' conduct from also being a cause of plaintiffs' injuries. See Czarney v. Porter, 166 Ohio App.3d 830, 833 (8th Dist. 2006) ("It is well established that two factors can combine to produce damages or illness, each being considered a proximate cause of the injury.").

c. Gross Negligence

Gross negligence in Ohio is "the failure to exercise any or very slight care" or "a failure to exercise even that care which a careless person would use." Posen v.

Sitecon, L.L.C., 8th Dist. No. 86239, 2006-Ohio-3167. Plaintiffs maintain that the master complaint adequately describes how these breaches proximately caused their injuries and that defendants' actions "went beyond mere thoughtlessness, inadvertence or error of judgment," but rather "constituted such utter disregard for the rights of others, and such utter disregard for prudence, that they amount to complete neglect of the safety of patients." Id. at ¶¶ 236-239. Bulk ordering of compounded pharmaceuticals for epidural injection under false names, and concealing the nature of the drugs used from the patients, would constitute a failure to exercise "even that care which a careless person would use."

2. Violation of Ohio's Consumer Sales Practices Act (Count IV)

The Ohio Consumer Sales Practices Act ("OCSPA") specifically exempts transactions between physicians and their patients, as plaintiffs conceded at oral argument. R.C. 1345.01(A); Docket # 1513, Transcript of Status Conference and Motion Hearing held on Oct. 23, 2014, at pg. 72. The Consumer Sales Practices Act claims against Drs. Batra and Kataby are therefore dismissed.

Defendant BKC Pain Specialists, LLC, however, is not a physician, and thus must comply with OCSPA. See Monroe v. Forum Health, No. 2012-T-0206, 2012-Ohio-6133, slip op. at 10 (Ohio Ct. App. Dec. 24, 2012). Plaintiffs allege that BKC, acting through Drs. Kataby and Batra, made false representations about the product actually used (NECC's MPA) by representing, among other things, that the patients "were receiving FDA-approved Depo-medrol when in fact [defendants] injected [plaintiffs] with NECC's compounded MPA." Master Compl. ¶¶ 243, 247, 251, 253. Such allegations

are supported, if not proven, by subsequent invoices issued by BKC for Depo-medrol rather than MPA. The plaintiffs have therefore adequately plead a cause of action against BKC under OCSPA.

3. Ohio Product Liability Act (Count IX)

Defendants assert that they cannot be subject to strict liability because each was a "provider of professional services who, incidental to a professional transaction the essence of which is the furnishing of judgment, skill, or services, sells or uses a product" and therefore exempt from liability under the Ohio Product Liability Act ("OPLA"). O.R.C. § 2307.71(A)(15)(b). As to Drs. Kataby and Batra, the court agrees. As to BKC, no such statutory exception applies. See Saylor v. Providence Hosp., 113 Ohio App. 3d 1, 5-8 (1996) (holding hospital could be liable to patient under OPLA for inadequate warning of use of non-FDA-approved surgical screws).

4. Failure to Warn (Count VIII)

Negligent failure to warn in Ohio is (1) a duty to warn; (2) a breach of that duty, and (3) the plaintiff's injury proximately resulted from the breach of duty. In re Whirlpool Corp. Front-Loading Washer Products Liab. Litig., 722 F.3d 838, 853 (6th Cir. 2013).

The 2005 amendment to OPLA explicitly abrogates all common law products liability failure to warn. See Wimbush v. Wyeth, 619 F.3d 632, 639 (6th Cir. 2010) ("the 2005 amendment expressly abrogated all common law product liability claims.") Because BKC did not render any services, at most it could be liable for product liability failure to warn. Because such claims are abrogated, plaintiffs' failure to warn claim against BKC, as separate from their OPLA claim, is dismissed.

To the extent plaintiffs also assert that Drs. Batra and Kataby failed to inform them that they were being administered "an unsafe, unreasonably dangerous drug compounded by NECC," and that the consent forms they provided "failed to inform [plaintiffs] of the risks and benefits of the procedure[] before it was performed," Master Compl. ¶ 301-302, those claims are identical to their common law negligence claims.

Plaintiffs' claims for failure to warn (Count VIII) are dismissed.

5. Punitive Damages (Count XIV)

In Ohio, punitive damages may be awarded when the defendant acted with "actual malice." Preston v. Murty, 32 Ohio St.3d 334, 334-335 (1987). Actual malice in the defendant means either "that state of mind under which a person's conduct is characterized by hatred, ill will or a spirit of revenge" or "a conscious disregard for the rights and safety of other persons that has a great probability of causing substantial harm." Id.

The master complaint includes various assertions that defendants' actions "went beyond mere thoughtlessness, inadvertence or error of judgment," Master Compl. at ¶ 237, and "constituted such utter disregard for the rights of others, and such utter disregard for prudence, that they amount to complete neglect for the safety of patients," id. at ¶ 239. Plaintiffs also allege that defendants willfully and knowingly failed to abide by consumer safety regulations and withheld important safety information from patients. Id. at ¶ 249-50. Plaintiffs further allege the BKC defendants bulk-ordered compounded pharmaceuticals from a pharmacy of known questionable quality under fake names in violation of state regulations, in order to save money. Such allegations are enough to

sustain plaintiffs' punitive damages claims at this early stage.

IV. Conclusion

Defendants' motion to dismiss (Docket # 896) is ALLOWED as to Counts IV and IX as against Batra and Kataby and ALLOWED as to Count VIII. The motion is DENIED as to all other claims.

January 13, 2015
DATE

/s/Rya W. Zobel
RYA W. ZOBEL
UNITED STATES DISTRICT JUDGE